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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,483	03/23/2007	Robert Michael Buch	CU60828	9640
20462 7590 09/17/2009 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				
			EXAMINER	
			SUTTON, DARRYL C	
		ART UNIT	PAPER NUMBER	
		1612		
		NOTIFICATION DATE	DELIVERY MODE	
		09/17/2009		ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary

Application No.

10/599,483

Applicant(s)

BUCH ET AL.

Examiner

DARRYL C. SUTTON

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-8 and 10-58 is/are pending in the application.
- 4a) Of the above claim(s) 8,16,17,19,21-24,27-29 and 47-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,10-15,18,20,25,26 and 30-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the amendment filed 06/22/2009. No new claims have been added. Claims 2-4 and 9 have been cancelled.

Applicant's arguments filed 06/22/2009 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Objections

Claim 1 and 35 are objected to because of the following informalities: Applicant has indicated in the Remarks that the term "or any derivative thereof" has been removed, but it is not crossed out as are all of the other terms that have been deleted. Appropriate correction is required. The Examiner recommends maintaining the same practice of indicating removed material throughout the entire claim listing, i.e. by placing terms in brackets and crossing them out.

Claim Rejections - 35 USC § 103

Claims 1, 10-14, 20, 25, 26, 30 and 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. (US 2002/097181).

Applicant argues that Godbey et al. does not disclose an alkyl vinyl ether/maleic acid anhydride copolymer or a combination of PVP and said copolymer. Based on the long list of polymer choices, one of skill in the art would not be directed to a composition comprised of the combination of the two water-soluble or water dispersible polymers.

The Examiner disagrees.

As cited by the Examiner in the Non-final office action, Godbey teaches that polymers suitable for the adhesive include maleic anhydride, methyl vinyl ether, ethyl vinyl ether and N-vinyl pyrrolidone, see page 7, last paragraph - page 8. As cited by Applicant on page 10 of the Remarks, Gantrez^R is a well known alkyl vinyl ether/maleic anhydride copolymer. In fact, Gantrez^R is a well known alkyl vinyl ether/maleic anhydride copolymer which is used in oral gel compositions in order to enhance adherence of whitening strips to teeth (See Sagel, 6,582,708, column 7, lines 9-25). Therefore, one of ordinary skill would have been motivated to utilize the maleic anhydride and the alkyl vinyl ether compounds in a copolymer form since the combination is an art recognized copolymer for adhesion to teeth. Further, as cited by Applicant on page 10, last paragraph of the Remarks, PVP is a preferred carrier for the invention of Godbey. Therefore, it would have been obvious to combine the alkyl vinyl

ether/maleic anhydride copolymer with PVP to serve as a carrier which also provides adhesion to the teeth.

Claim 33 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. (US 2002/097181) in view of Sagel et al. (US 6,582,708).

Applicant argues that the although Sagel discloses tooth whitening strips with a thickness of less than about 1000 μm , the dimensions are relevant to strips containing shallow pockets which provide additional reservoirs for the active substance. In addition, the hydrogen peroxide active agent is delivered as a part of an aqueous gel. Neither of these disclosures is in any way relevant to the dissolvable whitening strip claimed.

The Examiner disagrees.

While the Examiner agrees that the dimensions are relevant to strips containing shallow pockets which provide additional reservoirs for the active substance, one of ordinary skill in the art would be motivated to at least try to produce a strip of that thickness since the dimensions are art recognized, regardless of how the whitening agent is delivered to the teeth. Further, Sagel teaches the preferred dimensions for both the layer of gel and the substrate which make up the whitening strip, i.e. from about 0.07 mm to about 0.5mm and from about 0.005 to about 0.02 mm (column 4, lines 10-17 and column 9, lines 1-3). Combined the preferred thickness of the strip would be from about 0.075 mm to about 0.52 mm, i.e. from about 75 μm to about 520 μm , which read on instant claim 33 and which are still less than the

1000 μm cited by the Examiner in the Non-final office action.

Claims 5 and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. (US 2002/097181) in view of Rudy et al. (US 4,971,782).

Applicant argues that Rudy discloses a method for stabilizing a peroxide composition in an oleophilic material, in contrast to the instant invention which utilizes water soluble or water dispersible polymers, the opposite of oleophilic.

The Examiner disagrees.

While the Examiner agrees with the disclosure for one possible embodiment of Rudy et al. cited by Applicant, Rudy et al. clearly teaches that the peroxide can be encapsulated by a water soluble, water dispersible or water emulsifiable coating see page 10, Non-final office action.

Claims 15, 18, 27, 32 and 34-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. (US 2002/097181) in view of Sagel et al. (US 6,582,708).

Applicant argues since Godbey et al. does not disclose a combination of PVP and an alkyl vinyl ester/maleic anhydride copolymer, that even if Ruby, used for teaching encapsulation, and Perna, used for teaching multiple layers, were combined with Godbey, the instant invention would not be achieved.

The Examiner disagrees.

The Examiner's response to the argument concerning Godbey is provided above. Since, the prior art are all related to the whitening strip art, motivation for combining them exists and the combination reads on the instant invention.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612